Board of Pharmacy

Initial Statement of Reasons

Hearing Date: July 27, 2011

Subject Matter of Proposed Regulation: Notice to Consumers; Requirements

Sections Affected: Amend 16 Cal.Code Reg. § 1707.2
Add 16 Cal.Code Reg. § 1707.6

Specific Purpose of the Proposed Changes:

The Board of Pharmacy ("board") proposes to amend Section 1707.2 and add Section 1707.6 to Article 2 of Division 17 of Title 16 of the California Code of Regulations ("CCR") for the purpose of revising and recasting the "Notices to Consumers" that are required to be available in all California pharmacies. Existing law at Business and Professions Code Section 4122 requires every pharmacy to prominently post in a conspicuous place and readable by prescription drug consumers a notice that is produced and provided by the board. That section describes the general content areas of the notice and requires the board to adopt the wording of the notice by regulation. The board currently produces and distributes two "Notices to Consumers" – the contents of which are specified in 16 CCR Section 1707.2(f) and (g). The notices are produced and printed by the Board of Pharmacy and are distributed to pharmacies at no cost to the pharmacy. The notices are also available on the Board of Pharmacy's Web site in a portable document format (PDF).

Proposed amendments to Sections 1707.2(f) and (g) would consolidate existing consumer notices and move all requirements for consumer notices into one new proposed Section at 1707.6. Specifically, the existing regulations provide notice to consumers about the availability of prescription price information, the possibility of generic drug product selection, and talking to a pharmacist so that the patient can thoroughly understand how to take their medication(s) appropriately. This proposed regulation would revise or re-phrase this information and would place those notices in a new section at 1707.6(b).

Existing regulations at 16 CCR Section 1707.2(g) specify the content of a second "Notice to Consumers," which includes notice of a patient's rights concerning medicine and devices that are prescribed to them and the right to have their prescription(s) returned to them or transferred to another pharmacy if the pharmacy is unable to fill the prescription. This proposed regulation would revise or re-phrase this information and would place this notice in a new section at 1707.6.(b).

Existing law sets forth the requirements for a prescription drug container label for any drug dispensed to a patient in California (Business and Professions Code section 4076). On January 1, 2011, the board's regulation at Title 16, California Code of Regulations (CCR) Section 1707.5 became effective. This regulation established requirements for a patient-centered prescription drug container label, to include minimum font size for some items on a prescription drug container label, the format of the prescription drug container label, a patient's right to receive oral language interpretive services, and other requirements. The regulation also specifies that a patient can request that the pharmacy provide them with a prescription drug container label that has larger (12-point) font on the label (as an alternative to the minimum 10-point font) for specific "patient-centered" items on the label. However, current law does not require pharmacies to post notices to consumers informing consumers of their rights under this newly adopted regulation. This proposal would implement such a requirement.

Existing regulations from subdivisions (a) through (e) at Section 1707.2 of Title 16 of Division 17 of the California Code of Regulations specify a pharmacist's duty to consult a patient or the patient's agent. This proposal does not modify existing requirements regarding a pharmacist's duty to consult.

Specifically, this proposed regulation would add Section 1707.6 to Article 2 of Title 16 of Division 17 of the California Code of Regulations. Subdivision (a) of the proposed regulation would specify that every pharmacy shall prominently post in a place conspicuous to and readable by a prescription drug consumer a notice, as specified, unless the pharmacy receives approval from the Board of Pharmacy to display the content in another format or display methodology. This subdivision would delegate the board's authority to approve such formats or methodologies to the Executive Officer or to a committee of the board. Further, and as an alternative to displaying a printed version of the notice provided by the board, the proposed regulation authorizes a pharmacy to display the notice on a video screen, so long as the video screen is in a place that is conspicuous to and readable by prescription drug consumers. This proposed regulation specifies the minimum size of the video screen; requires that the video image of the board's notice be displayed; the length of time that the notice shall be displayed on a video screen, and the maximum amount of time that may lapse between the final screen of the notice, and the time that the notice re-displays.

As described above, this proposed regulation would add Section 1707.6 subdivision (b) to specify the content of the Notice to Consumers that shall be developed by the board and made available to pharmacies. This subdivision incorporates the requirements of Business and Professions Code Section 4122(a).

This proposed regulation would add Section 1707.6 subdivision (c) to require that a pharmacy post or provide to a prescription drug consumer a notice regarding the consumer's right to interpreter services upon request, at no cost to the consumer. This proposed regulation specifies that the text of the notice be repeated in at least 12 languages (Arabic, Armenian, Cambodian, Cantonese, Farsi, Hmong, Korean, Mandarin, Russian, Spanish, Tagalog, and

Vietnamese) and positioned in a manner so that a consumer can easily point to and touch the statement identifying the language in which he or she is requesting assistance. The proposed regulation would require a pharmacy to use a standardized notice that is made available by the Board of Pharmacy, unless the pharmacy has received the board's approval to display the notice in another format or display methodology. The proposed regulation would delegate the board's authority to approve such formats or methodologies to the Executive Officer or to a committee of the board. As proposed, if the pharmacy wishes to use a flyer or handout notice, the regulation would specify the minimum size of the flyer or handout to be at least 8 ½ inches by 11 inches, and that it shall be clearly visible to and kept within easy reach of each pharmacy counter where dangerous drugs are dispensed or furnished. The proposed regulation also mandates that the notice be available at all hours that the pharmacy is open.

Factual Basis/Rationale

Business and Professions Code section 4005 generally authorizes the board to amend rules and regulations necessary for the protection of the public pertaining to the practice of pharmacy and the administration of Chapter 9 of Division 2 of the Business and Professions Code.

Business and Professions Code section 4076.5 requires that the board adopt by regulation a standardized, patient-centered, prescription drug label for all prescription medicine dispensed to patients in California. This section further provides the board with the authority grant exemptions from the patient-centered prescription drug label regulations, as specified; and places reporting requirements on the Board of Pharmacy.

Business and Professions Code 4122 generally specifies that a pharmacy shall post in a place conspicuous to, and readable by, prescription drug consumers a notice provided by the board, with content specified in statute. This section also specifies requirements related to a consumer's right to the current retail price of a drug sold at the pharmacy.

On January 1, 2011, the board's regulation at 16 CCR § 1707.5 became effective, establishing requirements for a patient-centered prescription drug container label. The board discussed during that rulemaking the need to advise consumers of their rights related to the patient-centered drug container label requirements and first considered possible language for such a notice at its July 2010 Board Meeting.

The board worked on possible language for this proposed rulemaking from July 2010 through March 2011, finally approving proposed language to be noticed at its March 30, 2011 board meeting. During this time, the Board received much public comment and support for the need to provide written notices to consumers regarding their rights to request 12-pont font on their prescription drug container labels and have access to oral interpreter services. The board had many discussions with the public on this current proposal that resulted in changes to the original proposal to address areas of concern, including: that the regulations need to identify the specific languages available for interpretive service at pharmacies and that the board maintain the readability of the proposed notice while communicating the most important

information to the consumers. During the development of this proposal it also became clear to the board that existing notices to consumers needed to be consolidated so that information regarding a consumer's rights under the Pharmacy Law can be more effectively communicated to consumers at pharmacies.

This regulatory proposal is necessary to help keep consumers informed about their rights and to effectively implement the board's requirements regarding patient-centered prescription drug container labels. Prescription drug consumers benefit from knowing information about prescription drug therapy, their rights to have larger font sizes on their prescription drug container labels and the availability of interpretive services at the time when they are obtaining prescription medications. Placing the notices to consumers in the pharmacy where they are available at the time a patient needs or wants information provides prescription drug consumers with information relative to their rights, the services provided by the pharmacy, and information to help them understand their prescription medications and how to take them efficaciously. The Notices to Consumers also foster a quality dialogue between pharmacists and patients (or the patient's agent).

Underlying Data

1. Relevant Meeting Materials and Minutes from the Board Meeting held July 28-29, 2010
2. Relevant Meeting Materials and Minutes from the Legislation and Regulation Committee Meeting held July 19, 2010
3. Relevant Meeting Materials and Minutes from the Board Meeting held October 20-21, 2010
4. Relevant Meeting Materials and Minutes from the Board Meeting held February 1-2, 2011
5. Relevant Meeting Materials and Minutes from the Board Meeting held March 30, 2011
6. California Department of Health Services MMDC All Plan Letter 02003 dated June 7, 2002 Regarding Cultural and Linguistic Contractual Requirements: Threshold and Concentration Standard Languages Update; and Attached Chart Entitled "Threshold and Concentration Standard Languages for Two Plan, GMC, and COHS Counties" Dated May 2002
7. Relevant Meeting Materials and Minutes from the Board Meeting held May 3-4, 2011
8. Senate Bill 472 (Corbett) – Chapter 470, Statutes of 2007
9. Effect of Content and Format of Prescription Drug Labels on Readability, Understanding, and Medication Use: A Systematic Review, The Annals of Pharmacotherapy, 2007 May, Volume 41
10. Shrank, William H., MSHS, MD; Agnew-Blais, Jessica, BA; Choudhry, Niteesh K., MD PhD; Wolf, Michael S., PhD, MPH; Kesselheim, Aaron S., MD, JD; Avorn, Jerry, MD; Shekelle, Paul, MD PhD. ***The Variability and Quality of Medication Container Labels.*** ARCH INTERN MED/VOL 167 (No. 16), September 10, 2007
11. Improving Prescription Drug Container Labeling the United States, A Health Literacy and Medication Safety Initiative. A White Paper commissioned by the American College of Physicians Foundation, October 12, 2007

12. Language Services Resource Guide for Pharmacists, February 2010, Prepared by The National Health Law Program with the American Association of Colleges of Pharmacy National Alliance of State Pharmacy Associations

Business Impact

The board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. This initial determination is based on the fact that the proposed regulation does not impose a new requirement on a pharmacy licensed with the Board of Pharmacy; rather, it proposes to modify the existing Notices to Consumers that is produced by the Board of Pharmacy and distributed to licensed pharmacies at no cost to a pharmacy. As an alternative to posting the notice provided by the board, the proposal would allow a business to utilize alternative means to display a required notice in an alternative format, display methodology or via video screen, as specified.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

The board estimates this proposal could result in a fiscal impact to the Board of Pharmacy of approximately $20,000 to publish and distribute the revised "Notice to Consumer" posters to pharmacies. This is an important consumer education tool and the board will absorb these costs within its existing resources.

The only alternative would be to not pursue this regulation. This alternative is not reasonable because the board believes that patients have a right to know that they can ask for larger print on their prescription drug container labels, and also that they have the right to interpretive services at no cost to the patient. In addition, the proposed regulation would allow a pharmacy to provide the Notices either by posting the notices provided by the board (at no cost) or – if the pharmacy desires – to utilize a different format or display methodology.

No reasonable alternative to adopting or amending the regulations would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected private persons than the proposed regulations.